REMARKS

Regarding the Status of the Claims:

Claims 1, 3 – 14, 16 – 18, 22 – 34 are currently pending.

Claims 1, 3 – 19 and 21 – 24 stand rejected.

Claims 2, 15, 19, 20, and 21 are canceled.

Claims 28 – 34 are added.

Claims 25 and 26 are withdrawn from consideration.

Regarding the Claim Amendments presented in this reply:

The amendments to the claims do not add new matter.

- Claim 1 is amended. Support for the amendments to claim 1 can be found in the specification in at least Table 12.
- Claims 3 and 4 are amended to correct typographical errors.
- Claim 28 is new. Support for claim 28 can be found in the specification in at least Page 6, lines 32 – 41; Page 7, lines 10 – 20.
- Claim 29 is new. Support for claim 29 can be found in at least page 5, lines 16 – 27.
- Claim 30 is new. Support for claim 30 can be found in at least original claim 8, and page 7, lines 10 – 20.
- Claim 31 is new. Support for claim 31 can be found in at least original claim 9, and page 7, lines 39 – 40.
- Claim 32 is new. Support for claim 32 can be found in the specification in at least Page 6, lines 13 – 14; and Tables 1, 3, 5, 7, 9, and 11.
- Claim 33 is new. Support for claim 33 can be found in the specification in at least Tables 1, 3, 5, 7, 9, and 11.
- Claim 34 is new. Support for claim 34 can be found in the specification in at least Page 9, line 41 – Page 10, line 2, and in the original claims.

Regarding the Claim Rejection:

The Office action mailed February 26, 2007, rejected claims 1, 3 – 19, and 21 – 24 under 35 U.S.C §103(a) over DE 197 09 663 A1 to Kolter, for which US 6,066,334 is relied on as a translation (hereinafter, "Kolter") and US 4,837,032 to Ortega (hereinafter, "Ortega").

Applicants have defined "delayed release" in Claim 1 to address the BPAI's concern regarding the usage of this phrase as limiting active ingredient release.[1] This further takes Kolter out of the realm of delayed release and clearly makes the disposal of over 98% of the active ingredient in the first hour not a "delayed release" as presently defined.

While applicants do not concede that any amendment is necessary to overcome the aforementioned rejection, applicants, in the interest of progressing prosecution, make a further amendment to clarify the scope of the claims. Claim 1 is amended to state that a "pre-formulated" mixture is required. This amendment takes the claim outside the scope of Ortega.

Therefore, it is now appropriate to reexamine if in fact, with these alterations, the combination of Kolter and Ortega is valid.

The scope and contents of the cited references:

Kolter deals with the quick release of active ingredients. Specifically, the examples of the invention in Kolter show that greater than 98% of the active ingredient is released in the first 30 minutes.[2] Further, Kolter deals with the use of polymer powders as binders and includes the use of polyvinyl acetate, N-vinylpyrrolidone-containing polymer and another water soluable or water swellable substance amongst other additives.[3] Still further, Kolter is an invention relating to forming a tablet as the final

[1] Appeal 2008-3377 Pgs. 8 – 9.
[2] Kolter Examples 1 – 6.
[3] Kolter Claim 1.

product[4].

Ortega deals with the dispersion of an active ingredient that is retarded by the use of a formulation involving the active ingredient, a water insoluble polymer, a water soluble polymer, and an acid insoluble polymer among other additives. These are combined in a single tablet to disperse the active ingredient. The Ortega reference also deals with primarily homogenous tablets.

Differences between the combination of references and the claims in issue:

Claim 1: The present application uses a pre-formulated mixture of polyvinyl acetate and polyvinylpyrrolidone that is mixed with one or more active ingredients and a water soluble polymer or lipophilic additive amongst other additives. However, due to the pre-formulation of the polyvinyl acetate and the polyvinylpyrrolidone, the physical properties of the resulting matrix differs from Ortega. The matrix in the present application further relates to the delayed release of the active ingredients with no more than 25.3% active ingredient being released after an hour. This is a marked distinction from Kolter.

Claim 31: The present application encompasses the making of the dosage from by extrusion or melt extrusion to create an extrudate that is outside the scope of both Kolter and Ortega.

Claim 29: The present application encompasses the use of chemicals as the water soluble or lipophilic additive that are not contemplated by Kolter or Ortega. These polymers are polyethylene glycols, polyoxyethylene/polyoxypropylene block copolymers, and vinyl acetate/vinylpyrrolidone copolymers. Claim 29 is outside the scope of both Kolter and Ortega.

Claim 30: The present application encompasses the use of chemicals as the water soluble or lipophilic additive that are not contemplated by Kolter or Ortega. These lipophilic additives are fatty alcohols, fatty acid esters and fatty alcohol esters, glycerides,

[4] Kolter Column 5, lines 1 – 5.

waxes, and lecithin. Claim 30 is outside the scope of both Kolter and Ortega.

Claims 32 and 33: The present application supports the formation of dosage forms that exhibit the physical characteristics exhibited in these claims, namely higher hardness and friability factors. The formulations that are presented in Kolter and Ortega possess different physical characteristics than the dosage forms according to the present invention.

Claim 34: Claim 34 is drawn to an oral dosage form with a core and a coating that are substantially composed of different compounds. Ortega does not allow for the creation of a core and coating due to the lack of a pre-formulated mixture of polyvinyl acetate and polyvinylpyrrolidone. Further, Kolter and Ortega are drawn to single tablets that are primarily homogenous and therefore, Claim 34 is outside the scope of both references.

Non-Obviousness of Claimed Subject Matter:

The claims of the present application require that not more than 25.3% of the active ingredient is released in the first hour. This is contrary to Kolter where the slowest release provided for in the disclosure is 98.8% of the active ingredient released in the first **30** minutes. According to Kolter, almost the entire amount of active ingredient is released in half of the defined time. With this stark distinction, it is respectfully submitted that a skilled artisan would not look to Kolter to determine how to create an oral dosage form that releases, at most, 25.3% of the active ingredient after an entire hour. Rather, Kolter shows how to use similar polymers to facilitate a very quick release of greater than 98% of the active ingredient in a mere half hour. Therefore, there would be no motivation to combine Kolter with Ortega, if anything, Kolter teaches away from using these polymers in a manner required by the current claims. It is therefore respectfully submitted that there is no motivation for a skilled artisan to look to Kolter to create an oral dosage form requiring less than 25.3% of the active ingredient to be released in the first hour.

Kolter teaches a dosage form comprising a pre-formulated mixture of polyvinyl acetate and a derivative of polyvinylpyrrolidone. As Kolter states, "[t]he amount and nature of the binder, but also the processing method, crucially influence the properties of solid presentations, eg....the properties of compacts produced therefrom, such as breaking resistance, friability, disintegration and release of the active ingredient."[5] The presence of the pre-formualted mixture of polyvinyl acetate and polyvinylpyrrolidone crucially influences the properties of the solid presentations. Ortega teaches a dosage form including a mixture of polyvinyl acetate and polyvinylpyrrolidone that is not pre-formulated. Since Ortega does not relate to pre-formulated mixtures, Ortega provides no apparent reason to modify the amount of a pre-formulated mixture of polyvinyl acetate and polyvinylpyrrolidone in Kolter.

The dosage forms of claims 32 and 33 require physical characteristics that are not disclosed by Kolter or Ortega. Thus, a *prima facie* case of obviousness cannot be established with regard to these claims.

Independent claim 34 requires the use of a core and a coating, each respectively containing primarily active ingredient and primarily pre-formulated mixture. The references provide no apparent reason to arrive at this feature.

In Conclusion:

The present application is in condition for allowance. Applicants request favorable action in this matter. In order to facilitate the resolution of any issues or questions presented by this paper, the Examiner is welcome to contact the undersigned by phone to further the discussion.

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Respectfully submitted,
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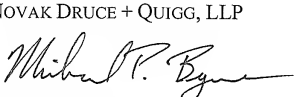

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[5] Kolter et al Column 1, line 21 – 28.